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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/602,546   | 06/23/2003  | Joan M. Henson       | A-72343 (470425-18) | 1218             |
| 32940  | 7590        | 05/03/2006           | EXAMINER            |                  |
| DORSEY & WHITNEY LLP<br>555 CALIFORNIA STREET, SUITE 1000<br>SUITE 1000<br>SAN FRANCISCO, CA 94104 |             |                      | MARX, IRENE         |                  |
|  |             |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 1651                |                  |

DATE MAILED: 05/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/602,546             | HENSON ET AL.       |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Irene Marx             | 1651                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 15 March 2006.
- 2a) This action is **FINAL**.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 11 and 12 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-10 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

|   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

The application should be reviewed for errors.

To facilitate processing of papers at the U.S. Patent and Trademark Office, it is recommended that the Application Serial Number be inserted on every page of claims and/or of amendments filed.

Applicant's election without traverse electing to prosecute the invention of Group I, claims 1-10 on 3/15/06 is acknowledged.

Claims 1-10 are being considered on the merits. Claims 11-12 are withdrawn from consideration as directed to a non-elected invention.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague, indefinite and confusing in that the degree of "stress tolerance" intended cannot be readily assessed. Moreover, the nature of the "stress" to be tolerated is unclear. Is it attack from fungi, from bacteria, from insects, from nematodes, from mollusks? Which ones? Is it nutrient-poor soils, high pH, low pH, heat, cold, high salt, drought, excessive water, competition from weeds, pesticide application, etc.?

Claim 10 is confusing in that a "seedling" is not properly a "part" of a plant.

Therefore, the metes and bounds of the claims are not delineated with sufficient clarity.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to the use of a *Curvularia* strain to treat any plant to confer any stress tolerance by inoculating with *Curvularia*. In contrast, the specification only provides guidance for the use of one isolate, i.e., *Curvularia* isolate 1A15.1, obtained from geothermal soils. No guidance is presented regarding the structure/function relationship between members of the entire genus *Curvularia* obtained from other sources, i.e. not obtained from *D. lanuginosum* plants grown in geothermal soils, and the sole strain disclosed. The disclosed species is not representative of the genus *Curvularia*, the members of which are generally recognized to be plant pathogens. There is no clear indication that other *Curvularia* strains share common properties with the one strain obtained with respect to conferring “stress tolerance”. Thus it is not apparent that the disclosure provided is reasonably predictive of the activity of *Curvularia* strains obtained from such sources. No guidance is presented regarding the evaluation of *Curvularia* isolates selected at random for the required function.

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the claimed invention.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ a specific strain of *Curvularia*. It is not clear if the written description is sufficiently repeatable to avoid the need for a deposit. Further it is unclear if the starting materials were readily available to the public at the time of invention.

It does not appear that a deposit was made in this application as that meets all of the criteria set forth in 37 CFR 1.801-1.809. Applicant or applicant's representative may provide assurance of compliance with the requirements of 35 U.S.C § 112, first paragraph, in the following manner.

**SUGGESTION FOR DEPOSIT OF BIOLOGICAL MATERIAL**

A declaration by applicant, assignee, or applicant's agent identifying a deposit of biological material and averring the following may be sufficient to overcome an objection and rejection based on a lack of availability of biological material.

1. Identifies declarant.
2. States that a deposit of the material has been made in a depository affording permanence of the deposit and ready accessibility thereto by the public if a patent is granted. The depository is to be identified by name and address.
3. States that the deposited material has been accorded a specific (recited) accession number.
4. States that all restriction on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.
5. States that the material has been deposited under conditions that access to the material will be available during the pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 CFR 1.14 and 35 U.S.C § 122.
6. States that the deposited material will be maintained with all the care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case, for a period of at least thirty (30) years after the date of deposit for the enforceable life of the patent, whichever period is longer.
7. That he/she declares further that all statements made therein of his/her own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the instant patent application or any patent issuing thereon.

Alternatively, it may be averred that deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the purpose of Patent Procedure (e.g. see 961 OG 21, 1977) and that all restrictions on the

availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.

Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (accession) number, date of deposit, name and address of the depository and the complete taxonomic description.

In addition there is no clear indication on this record that mere inoculation with any strain of *Curvularia* would have the effect to conferring stress tolerance on any plant whatsoever for all of the myriad of stresses that affect diverse plants, such as infestation by fungi, bacteria, insects, nematodes, mollusks and other pests and environmental stresses such as nutrient-poor soils, high pH, low pH, heat, cold, high salt, drought, excessive water, competition from weeds, pesticide application, etc.

From the record of the present written disclosure, a single strain of *Curvularia* obtained as an endophyte of the plant *D. lanuginosum* in geothermal soils is shown to be have some effect in conferring limited stress tolerance in various plants. The stress tolerance appears to be related to drought and thermal stress. Therefore this is the only strain enabled by the present specification for the reduction of the specific stresses recited, i.e., drought and thermal stress, provided, of course, that all deposit requirements are met.

It would require undue experimentation for one skilled in the art to determine which other strains of *Curvularia* isolated from soils or plants would be suitable for the claimed invention, in view of the diversity of strains encompassed by *Curvularia* and the difficulty of assessing whether a given strain is or is not pathogenic against given plants and does, in fact, confer absolute stress tolerance to all plant, especially in the absence of a specific screening assay. *Ex parte Jackson*, 217 U.S.P.Q. 804 (Bd. App. 1982).

See *Genentech, Inc. v Novo Nordisk A/S*, 42 USPQ2d, 1001, 1005 (Fed. Cir. 1997) ("Tossing out the mere germ of an idea does not constitute an enabling disclosure"). Also, *In re Scarbrough*, 182 USPQ 298, 302 (CCPA 1974) ("It is not enough that a person skilled in the art, by carrying out investigations along the line indicated in the instant application, and by a great amount of work eventually might find out how to make and use the instant invention. The statute requires the application itself to inform, not to direct others to find out for themselves. *In re Gardner et al.*, 166 USPQ 138 (1970)").

Undue experimentation would be required to practice the invention as claimed due to the quantity of experimentation necessary; limited amount of guidance and limited number of working examples in the specification; nature of the invention; state of the prior art; relative skill level of those in the art; predictability or unpredictability in the art; and breadth of the claims. *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Thus, the scope of the claims is not commensurate with the teachings of enablement of the specification.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Hodges *et al.*

The claims are directed to a method to treating a plant by inoculating the plant or a part thereof with *Curvularia* to confer stress tolerance.

Hodges *et al.* teach a method to treating a monocot such as a grass by inoculating the plant or a part thereof with *Curvularia* (See, e.g., page 640, col. 1. paragraph 2). That stress tolerance is conferred at least to some extent is inherent in the method, since the same process step of inoculation is used as is claimed.

Claims 1-5 and 10 are rejected under 35 U.S.C. 102(a) as being anticipated by de Luna *et al.*

The claims are directed to a method to treating a plant by inoculating the plant or a part thereof with *Curvularia* to confer stress tolerance.

*de Luna et al.* teach a method to treating a monocot such as a grass (rice) by inoculating the plant or a part thereof with *Curvularia* (See, e.g., page 471, paragraph 3). That stress tolerance is conferred at least to some extent is inherent in the method, since the same step of inoculation is used, and is evidenced by the killing of weeds which are known to stress plants by competing therewith for nutrients, space and sunlight.

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over *de Luna et al.* taken with *Azevedo et al.*.

The claims are directed to a method to treating a plant by inoculating the plant or a part thereof with *Curvularia* to confer stress tolerance.

*de Luna et al.* teach a method to treating a monocot such as a grass (rice) by inoculating the plant or a part thereof with *Curvularia* (See, e.g., page 471, paragraph 3). Stress tolerance is conferred at least to some extent by resistance to *Curvularia* and the killing of competing plants such as weeds, which compete for nutrients, space and sunlight, for example.

The reference differs from the invention as claimed in that members of the dicots are not inoculated. However, *Azevedo et al.* teach that *Curvularia* are endophytic fungi of dicots, such as *T. grandiflorum*. The reference suggests the inoculation of the plants with *Curvularia* in their use as a biocontrol agent, which would remove stress from the plants (See, e.g., page 56, col. 1).

Accordingly, one of ordinary skill in the art would have had a reasonable expectation of success in using the strains disclosed by the references to confer stress tolerance to the same or additional plants, at least to some extent, including a monocot such as wheat and parts of plants such as seeds.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the process of *de Luna et al.* by inoculating *Curvularia* on further plants, such as wheat and dicots as suggested by the teachings of *Azevedo et al.* for the expected benefit of protecting plants from stress or conferring stress tolerance on the plants with the beneficial results of maximizing the yield of agronomically valuable plants such as rice, wheat and fruit trees.

Art Unit: 1651

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*Irene Marx*  
Irene Marx

Primary Examiner  
Art Unit 1651